

REMARKS

Applicants have amended claims 18, 26, 27, and 33; and have canceled claims 36, 37, 43, and 45-48. Claims 18, 24, 26-31, 33-35, 42, and 44, of which claims 18, 26, and 27 are independent form, are presented for examination.

As amended, the claims are directed to stents comprising a core having a first composition, a first layer on the core, and a barrier on the outer surface of the stent so that the first layer is isolated from a patient's blood. The first layer has a second composition that is different than the first composition and capable of increasing the visibility of the core to *in-vivo* viewing methods. The barrier comprises certain oxides, nitrides, or carbides.

Prior to this Amendment, claims 18, 24, 26-31, 33, 34, 36, 37, and 42-48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by U.S. Patent No. 6,099,561 (Alt). In particular, the Examiner has asserted that the oxides, nitrides, and carbides recited in the claims were well known in the art and would have been obvious variants in view of their similar purposes.

The Examiner's assertion that the claimed materials are well known in the art of stents is conclusory and unsupported by Alt. Nowhere does Alt disclose or suggest using the claimed oxides, nitrides, or carbides to produce a stent, as claimed. Indeed, Applicants do not dispute that the claimed oxides, nitrides, or carbides are known materials, but the issue is whether there is a suggestion in the art to use the claimed materials in a stent. Here, the Examiner has not provided such a suggestion in Alt or in any other reference. But if the Examiner is relying on Official Notice to support his position that the claimed materials are well known in the art of stents, then Applicants request that the Examiner provide one or more references to support that position so that the reference(s) may be addressed.

Instead, in asserting that the claimed materials are obvious variants of Alt's materials and therefore would have been obvious, the Examiner has improperly applied an obvious-to-try standard to reject the claims. Alt has disclosed a class of materials (an oxide, a hydroxide, or a nitrate of a noble metal) that includes a vast number of possible materials. But the fact that the claimed materials may be encompassed by a disclosed generic formula does not by itself render

those materials obvious. The Examiner is reminded that even when obviousness is based on a single reference, the Examiner still must show a suggestion or a motivation to modify the teachings of the reference to arrive at the claimed subject matter. Here, none of the claimed materials includes a noble metal so as to be encompassed by Alt's class of materials; and none of the claimed barrier materials includes or is similar to iridium oxide, the one example provided by Alt. Alt does disclose another preferred material (titanium nitrate), but this single example alone does not provide the requisite motivation to select the claimed barrier materials. One of skill in the art would recognize that the claimed devices are used *in vivo* and require strict biological compatibility balanced with strict mechanical performance. Many variables (such as strength, biocompatibility, visibility, and compatibility with other materials) are involved in selecting a suitable material. Given these strict requirements, one skilled in the art would recognize that just because one ceramic material is suitable, not every ceramic material would be suitable. The Examiner has suggested that Alt broadly invites one of ordinary skill to try all other ceramic materials, but this obvious-to-try standard is an improper basis to reject the claims.

The Examiner has also cited Applicants' own disclosure to show that other materials may be used as a barrier material. It is not clear why the Examiner has cited Applicants' disclosure in rejecting the claims, but it appears that the Examiner has used Applicants' specification as a source for the suggestion of trying out different barrier materials in making out the obviousness rejection. It is black letter law, however, that the Applicants' own disclosure cannot be used as a template for rejecting the claims.

In light of the above amendments and remarks, Applicants request that the rejection over Alt be reconsidered and withdrawn.

Claims 18, 24, 27, 28, 33-36, and 44-48 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,685,306 (Davidson); and claims 26, 29-31, 37, 42, and 43 under 35 U.S.C. § 103(a) as being unpatentable over Davidson. Davidson does not disclose or suggest a stent including a first layer that has a composition different than the composition of a core and capable of increasing the visibility of the core to *in-vivo* viewing methods, as claimed.

At best, Davidson describes a device having an alloy (e.g., Ti-Nb-Zr) core with a oxygen or nitrogen diffusion hardened surface and a ceramic coating. (See, e.g., Davidson, col. 11, lines 59-62.) Nothing in Davidson suggests that the diffusion hardened surface is capable of increasing the visibility of the core:

The resultant oxygen diffusion hardened implants are characterized in that the oxide film contains primarily a mixture of titanium and zirconium oxides in the implant surface. Niobium oxides may also be present. Immediately underlying this mixed-oxide film is sometimes a region of oxygen-rich metal alloy. Underlying the sometimes-obtained oxygen-rich alloy layer is the core Ti--Nb--Zr alloy. The interface between the sometimes-obtained oxygen-rich alloy layer and the oxide regions is typically zirconium-rich in comparison to the underlying Ti--Nb--Zr alloy. (Id. col. 7, lines 8-18.)

On the contrary, one would expect that diffusion hardening the core would reduce the visibility of the core because formation of the oxygen-rich alloy layer consumes a portion of the core and dilutes the portion with oxygen, which has a lower atomic number than titanium, niobium, or zirconium. While Davidson mentions that an interface between the oxygen-rich alloy layer and oxide regions is typically zirconium-rich, Davidson provides no indication or suggestion (e.g., thickness or composition) that the interface is capable of increasing the visibility of the core, as claimed. Since Davidson does not disclose or suggest a device having a first layer capable of increasing the visibility of a core to *in-vivo* viewing methods, Applicants request that the rejection be reconsidered and withdrawn.

Applicants believe the claims are in condition for allowance, which action is requested.

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Enclosed is a Petition for Extension of Time with the required fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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